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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|------------------------------------|----------------------|---------------------|------------------|
| 10/583,094 | 06/15/2006 | Werner Mederski | MERCK-3190 | 1255 |
| | 7590 03/16/200 TE, ZELANO & BRA | | EXAM | IINER |
| 2200 CLARENDON BLVD. | | | SAEED, KAMAL A | |
| SUITE 1400 ARLINGTON, VA 22201 | | | ART UNIT | PAPER NUMBER |
| | | | 1626 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 03/16/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
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| Office Action Occurrence | 10/583,094 | MEDERSKI ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Kamal A. Saeed | 1626 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | s | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be timil apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI | J. nely filed the mailing date of this commun D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | | | | | | |
| | | | | | | |
| 3) Since this application is in condition for allowan | | | | | | |
| closed in accordance with the practice under E. | x <i>parte Quayl</i> e, 1935 C.D. 11, 45 | i3 O.G. 213. | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-24</u> is/are pending in the application. | | | | | | |
| · · · · · · · · · · · · · · · · · · · | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) 1-24 are subject to restriction and/or e | lection requirement. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| ,— | ammor. Note the attached office | 7.00.017 01 101111 1 7 0 10 | ,2. | | | |
| Priority under 35 U.S.C. § 119 | | (1) | | | | |
| 12) Acknowledgment is made of a claim for foreign | priority under 35 U.S.C. § 119(a) | -(d) or (t). | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | have been made and | | | | | |
| 1. Certified copies of the priority documents | | NI | | | | |
| 2. Certified copies of the priority documents | | | | | | |
| 3. Copies of the certified copies of the priori | • | d in this National Stag | е | | | |
| application from the International Bureau | | ٦ | | | | |
| * See the attached detailed Office action for a list of | of the certified copies not receive | a. | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Da 5) Notice of Informal P | nte | | | | |
| Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 6) Other: | αιοπι πρριισαιίση | | | | |
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DETAILED ACTION

Claims 1-24 are pending in the instant application and are subject to the following lack of unity requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-16, 18-21 and 23, drawn to compounds and compositions of Formulas I, classified in various subclasses of classes 514, 544, 546 and 548.

Group II, claim 17, drawn to method of preparation of compounds of Formula I, classified in various subclasses of classes 514, 544, 546 and 548.

Group III, claim 22 and 24, drawn to a method of use of compounds of Formula I classified in various sub-classes of class 514.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking the claims is a compound with formula **III**. Prior art exists which causes the core structure in the current application to lack a special technical

feature. The core structure in this case is:

This structure has been

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seen in US 20070135507, which teaches a compound of Formula

linking the claims does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the art. Additionally, the variables found on the technical feature vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter.

Accordingly, Groups I-III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Therefore, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

Applicant is further required to elect a single disclosed species within the elected group and to provide the structure of this elected species. For example, if Group I is elected, applicant must further elect a single disclosed species with the Formula I. A single disclosed species of Formula I is required even if Group II or III is elected for prosecution.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: the various structurally different compounds of Formulas I.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: claims 1-16 and 18-21 are drawn to or involve the various structurally different compounds of Formula I.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: a compound of Formula I wherein X and X' are =C(H)- is structurally different than a compound of

Formula II wherein X and X' are =N- and these two compounds are, therefore, different species or they lack the same core structure or special technical feature.

Advisory of Rejoinder

The following is a recitation of M.P.E.P. 821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2); or (B) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the

limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that "[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee...will not entitle a party to a refund of such fee..." In this case, the fees paid under 37 CFR 1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101,102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action. Form paragraphs 8.42 through 8.44 should be used to notify applicant of the rejoinder of process claims which depend from or otherwise include all the limitations of an allowable product claim.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with M.P.EP 821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product

claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal A Saeed, Ph.D. whose telephone number is (571) 272-0705. The examiner can normally be reached on M-T 7:30 AM- 5:00 PM.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise requires a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

/Kamal A Saeed, Ph.D./

Primary Examiner, Art Unit 1626